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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
04/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,869	JANSEN ET AL.	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/8/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/8/11 has been entered.

Response to Amendment

In the reply filed 3/8/11, applicant amended claims 40 and 41. Claims 40-52 are currently pending.

Response to Arguments

Applicant's arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly considered prior art.

Specifically, applicant argues that Dudar and Larson do not reasonably suggest the device as claimed because Larson's sealing portion 66 does not have a diameter that continuously increases, but rather comprises a bulbous outer surface (page 8 of arguments). However, it is the examiner's position that Larson's rounded, bulbous

sealing portion 66 does in fact continuously increase in diameter in the proximal direction. *Applicant appears to be arguing that Larson's bulbous sealing portion does not have a constantly increasing diameter*, which is substantially different than a continuously increasing diameter.

Nonetheless, because Larson's sealing portion 66 is not conical, the rejection has been changed to include Brony (US 5,454,805) which reasonably suggests that the sealing portion of a vial access device may have a conical shape. See the rejection below.

Second, applicant argues that Larson's bulbous sealing portion 66 is not configured to penetrate the elastic stopper when the bead is disposed in the space, but rather is configured to limit penetration of the needle. This argument is not persuasive because, although Larson's sealing portion does in fact limit penetration of the needle, it does not *prevent* it. It can be clearly seen in figure 6 and column 4, lines 1-57 of Larson that the bulbous sealing portion substantially penetrates the elastic stopper to a degree. It is important to note that "limiting" penetration of the stopper is not the same as "preventing" penetration of the stopper.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, *the "conical sealing portion having a diameter that continuously increases from the cylindrical portion to a*

position proximate the lid portion" of Claim 40 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dudar et al. (US 5,211,638) in view of Larson (US 3,977,555), and further in view of Brony (US 5,454,805).

2. With respect to Claims 40-42, 44, and 48, Dudar et al. (hereafter 'Dudar') teaches a fluid transfer device comprising a lid portion 740 and an edge portion 738 formed integrally with said edge portion to form a receiving cap, and a piercing mandrel (754, 756) formed integrally therewith. The piercing mandrel comprises a piercing portion configured to pierce completely through the thickness of an elastic stopper (see Figures 34-36), said piercing portion comprising a pointed end 756 and a substantially cylindrical portion 738 (Column 12, Lines 39-50). The edge portion comprises an inward projection (764a-d) configured to center the bead as the bead is received within the interior space, as per Claim 42. Dudar teaches the device substantially as claimed, but does not specifically teach a conical sealing portion proximal of the piercing portion for sealing tears in the elastic stopper of the vial.

Larson teaches a vial adapter for transferring medical fluids comprising a piercing mandrel for puncturing the septum of a medical vial. The piercing mandrel comprises a piercing portion at the distal end thereof, said piercing portion comprising a pointed tip 40 and a cylindrical portion 38 of constant diameter. The piercing mandrel further comprises a sealing portion 66 disposed proximal of the piercing portion, the sealing portion comprising an enlarged diameter that adjoins the cylindrical portion 38 and widens towards the lid portion (specifically, the sealing portion has a bulbous shape continuously increases in diameter toward the proximal end thereof). The enlarged sealing portion serves to stretch the elastic stopper so as to ensure complete penetration by the needle-like piercing portion (see abstract), such that the sealing portion contacts the elastic stopper as the piercing portion pierces the stopper. This system also causes the enlarged diameter portion to be pressed firmly against the stopper, thereby creating a seal between the sealing portion and the stopper and sealing an opening within the stopper (Column 4, Lines 1-57) The use of an enlarged sealing portion on the proximal portion of a piercing mandrel is therefore known in the art. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the piercing mandrel of Dudar with Larson's enlarged sealing portion so as to ensure complete penetration of an elastic stopper when a medical fluid container is inserted into the interior space.

Further, although Larson does not specifically teach that the sealing portion having an increased diameter comprises a *conical* shape, Larson does provide sufficient motivation to provide an enlarged, continuously increasing diameter on the

proximal end of a piercing mandrel. Brony teaches a system for accessing a medical vial access system comprising a syringe 22 having conical shape that increases in diameter toward the proximal end thereof (see Figures 1 and 4). The conical shape is adapted to form a seal between the syringe and the stopper, such that fluid is prevented from leaking around the outer edges of the syringe (Column 4, Lines 48-65). It has been held that mere changes in shape do not constitute a patentable improvement in the art when said changes do not result in a nonobvious change in functionality (see MPEP 2144.04. IV. B.). In this case, Larson and Brony both teach vial access syringes having an enlarged section that continuously increases in diameter toward the proximal end, thereby causing the enlarged section to abut against the elastic stopper of a vial when the vial is accessed. Larson and Brony both suggest that this enlarged proximal region creates a seal between elastic stopper and the access device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer device of Dudar and Larson with a sealing portion having a conical shape, as suggested by Brony, thereby providing a well known, alternate means for preventing leaks through the elastic stopper.

3. With respect to Claim 43, Dudar teaches that the inward projection is further configured to engage the behind portion of the bead when the bead is substantially disposed in the space (see Figure 36).

4. With respect to Claims 45 and 46, Dudar teaches that the piercing mandrel is stationary relative to the lid portion. The inward projection radially surrounds the piercing mandrel (see Figures 34 and 35).

5. With respect to Claim 47, at least a portion of the piercing portion is disposed further away from the lid portion than the inward projection.

6. With respect to Claims 49 and 50, at least a portion (742, 746, and 748) of the edge portion extends away from the lid portion and inward projection. Specifically, the vial slots (766a-b) extend away from the inward projection along a direction that is parallel to the central longitudinal axis of the internal space. See Figures 35 and 36.

7. With respect to Claims 51 and 52, Dudar teaches that the free edge (746, 748, 766) has inner and outer diameters that are larger than the outer diameter of the rest of the edge portion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/
Examiner, Art Unit 3761